Complete Summary

GUIDELINE TITLE

Guidelines for point care testing: haematology.

BIBLIOGRAPHIC SOURCE(S)

Briggs C, Guthrie D, Hyde K, Mackie I, Parker N, Popek M, Porter N, General Haematology Task Force. Guidelines for point of care testing: haematology. London (UK): British Committee for Standards in Haematology; 2007 Jul 31. 29 p. [50 references]

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous version: Guide-lines for near patient testing: haematology. Near Patient Testing Working Party. General Haematology Task Force of BCSH. Thrombosis and Haemostasis Task Force of BCSH. Clin Lab Haematol. 1995 Dec;17(4):301-10.

The date for guideline review is 2009.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Any disease/condition for which hematologic testing is required, including:

- Diabetes
- Disseminated intravascular coagulation (DIC)
- Deep venous thrombosis (DVT)

- Hemoglobinopathies

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Screening

CLINICAL SPECIALTY

Critical Care
Emergency Medicine
Family Practice
Hematology
Internal Medicine
Nephrology
Pediatrics

INTENDED USERS

Clinical Laboratory Personnel
Health Care Providers
Hospitals
Managed Care Organizations
Pharmacists
Physicians
Public Health Departments
Utilization Management

GUIDELINE OBJECTIVE(S)

- To provide healthcare professionals in the United Kingdom with clear guidance on the management of point of care testing (POCT)* in haematology
- To provide a framework for the provision of appropriate local arrangements for POCT and to protect patients and staff
- To provide information and suggestions for good laboratory practice and for producing reliable results, regardless of where the test is performed

*POCT refers to any testing performed outside the hospital laboratory.

TARGET POPULATION

Patients in the United Kingdom who require blood tests

Note: This guideline does not cover patient self-testing.

INTERVENTIONS AND PRACTICES CONSIDERED

Point of Care Tests

1. Full blood counts with differential
2. Hemoglobin concentration
3. Coagulation tests (prothrombin time [PT], activated partial thromboplastin time [APTT], international normalized ratio [INR], activated clotting time)
4. D-dimer tests
5. Blood gas analysis
6. Hemoglobin A1c (HbA1c) measurement
7. Blood levels of low molecular weight heparin and platelet factor 4 heparin antibodies

Implementation of Point of Care Testing

1. Interdisciplinary committee oversight
2. Equipment procurement
3. Personnel training
4. Equipment calibration and maintenance
5. Risk assessment for equipment use
6. Development of standard operating procedures
7. Documentation and protection of analytical data
8. Documentation of quality control and quality assurance measures, including internal quality control, external quality assessment, internal audits
9. Accreditation
10. Cost-benefit analysis

MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of point of care testing

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For this updated guideline PubMed, MEDLINE and EMBASE were searched systematically for publications in English 1995 to 2006 using key words near patient testing and point of care testing.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Criteria used to quote levels and grades of evidence were as outlined in Appendix 7 of the Procedure for Guidelines Commissioned for the British Committee for Standards in Haematology (BCSH) (http://www.bcshguidelines.com/process1.asp#App7).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline group was selected to be representative of United Kingdom based clinical experts. The writing group produced the draft guideline that was subsequently revised by consensus by members of the General Haematology Task Force of the British Committee for Standards in Haematology.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was reviewed by a sounding board of approximately 100 United Kingdom haematologists, the BCSH (British Committee for Standards in Haematology) and the British Society for Haematology Committee and comments incorporated as appropriate.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

1. The purpose, nature and potential benefits of point of care testing (POCT) at a particular site should be defined before initiating the service.
2. A National Health Service (NHS) Trust POCT committee should be established and take responsibility for all POCT and ensure it is appropriate and accreditable. The committee should involve laboratory staff but also other relevant staff as appropriate. Where necessary there should also be a local point of care committee to oversee the service when it is in a non-hospital setting.
3. The advice and involvement of an accredited clinical laboratory should be sought in order to achieve optimum quality and cost-effectiveness. This is also the recommendation for non-NHS sites (pharmacies for example). The haematology laboratory should play a key part in maintaining standards for patients in their catchment area.
4. The POCT committee should be clear as to the purpose of the test: is it for diagnosis, screening for occult disease, monitoring disease or treatment?
5. The POCT committee should investigate the full costs of the service including purchase costs and revenue costs including the cost of staff training.
6. The POCT environment should be clean and well lit and may need temperature control. Service managers must perform a risk assessment of testing procedures. Equipment must be provided for the safe disposal of blood and contaminated consumables; staff must be trained in the use of this equipment.
7. Documentation must include the name of the operator, date, patient identity details, results, lot number of calibrant, reagents and quality control materials. This must be recorded at the same time of analysis. A record of any maintenance and repairs and should also be kept. It is advisable to keep an 'error log' to assist any investigation of potential incidents.
8. POCT raises the possibilities of litigation ensuing from erroneous results. Who bears legal responsibility locally should be established as well as the need for appropriate insurance coverage.
9. All staff must recognise that only trained operators may use the equipment. An up-to-date list of trained operators and competency training should be maintained.
10. POCT equipment should be uniform to allow simplification of training, storage and supply of reagents, servicing and maintenance.
11. Internal quality control (IQC) and external quality assessment (EQA) programmes must be established.
12. Since the problems arising from POCT are not inconsiderable, but can usually be overcome, the local haematologist and laboratory staff should be co-opted into the POCT service and involved in the ongoing provision of POCT.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Point of care testing may provide a more rapid service than can be achieved in the hospital laboratory.

POTENTIAL HARMS

Point of care testing may be less efficacious and have negative medicolegal and safety aspects.

QUALIFYING STATEMENTS

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- While the advice and information in these guidelines is believed to be true and accurate at the time of going to press, neither the authors, the British Society of Haematology nor the publishers can accept any legal responsibility for the content of these guidelines.
- In all cases individual patient circumstances may dictate an alternative approach.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

A diagram to illustrate the stages for the implementation of a Point of care testing (POCT) service is illustrated in Appendix 1 of the original guideline document.

Appendix 2 of the original guideline document provides details on operational evaluation of point of care testing.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 (revised 2007 Jul 31)

GUIDELINE DEVELOPER(S)

British Committee for Standards in Haematology - Professional Association

SOURCE(S) OF FUNDING

British Committee for Standards in Haematology

GUIDELINE COMMITTEE

British Committee for Standards in Haematology (BCSH) General Haematology Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Writing Group: Ms Carol Briggs, University College London Hospital, UK; Mr David Guthrie, Guy's & St Thomas' NHS Foundation Trust, London, UK; Dr Keith Hyde, Manchester Royal Infirmary, Manchester, UK; Dr Ian Mackie, University College London, UK; Dr Norman Parker, The Whittington Hospital, London, UK; Mrs Mary Popek, University College London Hospital, UK; Mr Neil Porter, The Royal Hallamshire Hospital, Sheffield

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available from the British Committee for Standards in Haematology Web site.

Print copies: Available from the British Committee for Standards in Haematology; Email: bcsh@b-s-h.org.uk.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on March 18, 2008. The information was verified by the guideline developer on April 1, 2008.

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